IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG and LTS LOHMANN THERAPIE-SYSTEME AG Plaintiffs, v. MYLAN INC. and MYLAN PHARMACEUTICALS INC. Defendants.	:	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and LTS Lohmann Therapie-Systeme AG, for their Complaint against defendants Mylan Inc. and Mylan Pharmaceuticals Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

6. On information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

7. On information and belief, defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc.

8. On information and belief, the acts of Mylan Pharmaceuticals Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Mylan Inc.

9. Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. are referred to collectively herein as "Mylan."

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. On information and belief, Mylan Pharmaceuticals Inc. is registered to conduct business with the State of Delaware and maintains as a registered agent Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

12. On information and belief, Mylan Pharmaceuticals Inc. is registered pursuant to Del. Code Ann. tit. 24, § 2540 to distribute its generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

13. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. are in the business of manufacturing, marketing, importing into the United States and selling pharmaceutical drug products, including generic drug products. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. market and sell drug products throughout the United States and in this judicial district, and have purposely availed themselves of the rights and benefits of Delaware law and this Court.

14. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, the above-mentioned facts.

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

16. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the United States Food and Drug Administration ("FDA") on July 6, 2007, and Exelon® Patch

(13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths) is sold in the United States by Plaintiff NPC.

17. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

18. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,316,023 ("the '023 patent"). The '023 patent was duly and legally issued on November 13, 2001.

19. The '023 patent claims pharmaceutical compositions, *inter alia*, comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition, as well as transdermal devices. A true copy of the '023 patent is attached hereto as Exhibit A.

20. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

21. The '031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as transdermal devices and methods of stabilizing (S)-N-ethyl-3-[(1-

dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form. A true copy of the '031 patent is attached hereto as Exhibit B.

22. The '023 and '031 patents were initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

23. On information and belief, Mylan submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths ("Mylan's ANDA Products") before the expiration of the '023 and '031 patents.

24. On information and belief, Mylan made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '023 and '031 patents are invalid and/or will not be infringed.

25. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Mylan's ANDA Products before the expiration of the '023 and '031 patents, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2).

26. On information and belief, when Mylan filed its ANDA, it was aware of the '023 and '031 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '023 and '031 patents was an act of infringement of those patents.

27. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's ANDA Products will infringe one or more claims of the '023 and '031 patents.

28. On information and belief, the commercial manufacture of Mylan's ANDA Products will involve direct infringement of the '023 patent. On information and belief, this will occur at Mylan's active behest, and with Mylan's intent, knowledge and encouragement. On information and belief, Mylan will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '023 patent.

29. On information and belief, the commercial manufacture of Mylan's ANDA Products will involve direct infringement of the '031 patent. On information and belief, this will occur at Mylan's active behest, and with Mylan's intent, knowledge and encouragement. On information and belief, Mylan will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '031 patent.

30. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mylan's ANDA Products be a date that is not earlier than January 8, 2019, the expiration date of the '023 and '031 patents, and an award of damages for any commercial sale or use of Mylan's ANDA Products and any act committed by Mylan with respect to the subject matter claimed in the '023 and '031 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

31. On information and belief, Mylan has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's ANDA Products, including seeking approval of that product under Mylan's ANDA.

32. There is a substantial and immediate controversy between Plaintiffs and Mylan concerning the '023 and '031 patents. Plaintiffs are entitled to declaratory judgment

under 28 U.S.C. §§ 2201 and 2202 that Mylan will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Mylan has infringed and induced infringement of one or more claims of the '023 and '031 patents by filing the aforesaid ANDA relating to Mylan's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths;

B. A permanent injunction restraining and enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of a rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths, as claimed in the '023 and '031 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Mylan's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths, be a date that is not earlier than the expiration of the right of exclusivity under the '023 and '031 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths, will infringe one or more claims of the '023 and '031 patents and that Mylan will induce infringement of one or more claims of the '023 and '031 patents;

E. Damages from Mylan for the infringement and inducement of infringement of the '023 and '031 patents;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: June 19, 2014

McCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com

Attorneys for Plaintiffs

Of Counsel:

Nicholas N. Kallas
Christopher E. Loh
Charlotte Jacobsen
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100
nkallas@fchs.com
cloh@fchs.com
cjacobsen@fchs.com